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Department of
Agriculture

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Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-27

Subject: Availability of Distemper Virus Aerosol Challenge

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

I. PURPOSE

This notice is to inform interested parties of the limited availability of distemper virus aerosol challenge for use in dogs and other carnivores from the Center for Veterinary Biologics (CVB).

II. BACKGROUND

References and reagents are provided as testing aids as described in the Code of Federal Regulations (9 CFR 113.2) and are provided to assist U.S. biologics manufacturers to meet codified requirements or as a service for agents or procedures without codified requirements. References and reagents are also provided, as a courtesy, to colleges, universities, international scientists, non-U.S. biologics manufacturers, other U.S. and foreign regulatory agencies, and to U.S. allied industries to assist with biological related projects.

Previously, the CVB had adequate volumes of distemper virus aerosol challenge for dilution and direct use. This reagent was initially established and validated to assist firms in complying with the then current regulations for the licensure of distemper virus products for dogs. Since the establishment of the last aerosol challenge in 1990, the regulations have been amended and the aerosol challenge removed as the method of challenge for dogs.

The supply of the distemper virus aerosol challenge is now limited and the Center does not intend to replace the reagent. The primary use recently has been for challenge of species other than dogs, for which the CVB has not established either a route or dosage level.



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(Voice/TTY/ASCII/Spanish)
1-800-877-8339

III. ACTION

Effective with this notice, the distemper virus aerosol challenge will be supplied as a seed for firms or interested parties to expand. Firms should expand the challenge and validate the route and dosage for the intended species. The CVB will provide information and advice for the expansion and validation upon request. Use of the expanded challenge material and challenge method in licensure of veterinary biologic products should be approved by the CVB prior to conducting studies.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

